### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Storer et al.

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FOR TREATING FLAVIVIRIDAE INFECTIONS

Examiner: T. McIntosh III

For: Modified 2' and 3' Nucleoside Prodrugs

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CAM:

**IDX 1018** 

# RENEWED REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT

**Mail Stop Petition** 

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

This Renewed Request for Reconsideration of Patent Term Adjustment is in response to the Decision on Request for Recalculation of Patent Term Adjustment in View of Wyeth mailed April 21, 2010 ("the April 21 Decision," a copy of which is attached as Exhibit A), and the Decision on Request for Reconsideration of Patent Term Adjustment mailed March 17, 2010 ("the March 17 Decision," attached as Exhibit B) in connection with the abovecaptioned patent.

The patent term adjustment under 35 U.S.C. § 154(b) indicated on the April 21 Decision is 1,922 days. The patent term adjustment under 35 U.S.C. § 154(b) indicated on the March 17 Decision is 1,420 days. As set forth below, it is believed that the correct patent term adjustment is 1,356 days.

The April 21 Decision states that Patentees are given one month or thirty days, which ever is longer, from the mail date of the decision to respond. Therefore, this Renewed Request for Reconsideration of Patent Term Adjustment is timely filed.

#### A. Statement of Facts Under 37 C.F.R. § 1.705(b)(2)

Pursuant to 37 C.F.R. § 1.702, Applicants submit the following statement of facts in support of this Application for Patent Term Adjustment. The patent term adjustment due to PTO delays is the sum of PTO delays under 35 U.S.C. § 154(b)(1)(A) and 35 U.S.C.

§ 154(b)(1)(B), minus Applicants' delay under 37 C.F.R. § 1.704. The details of this calculation are provided below.

## 1. Patent Office Delays Under 35 U.S.C. §154(b)(1)(A)

Applicants submit that the number of days of Office delay under 35 U.S.C. § 154(b)(1)(A) is 501 days. The filing date of the instant patent is June 27, 2003. Thus, a first action was due August 28, 2004, *i.e.*, the day after fourteen months after the date of filing. See 37 C.F.R. §1.703(a)(1) (patent term adjustment is equal to the number of days "in the period beginning on the day after the date that is fourteen months after the date on which the application was filed...and ending on the date of mailing of...an action under 35 U.S.C. §132...."); 35 U.S.C. 154(b)(1)(A)(i). A Restriction Requirement was not mailed until January 11, 2006. Thus, Applicants submit that the period of Office delay for failure to issue an action within 14 months is 502 days.

A Response after non-final Office Action was filed August 20, 2007. Thus, an Office Action under 35 U.S.C. § 132, or a Notice of Allowance under 35 U.S.C. § 151, was due December 21, 2007. See 37 C.F.R. § 1.703(a)(2) (patent term adjustment is equal to the number of days "in the period beginning on the day after the date that is four months after the date on which a reply under 37 C.F.R. 1.111 was filed and ending on the date of mailing of...an action under 35 U.S.C. 132...."); 35 U.S.C. § 154(b)(1)(A)(ii). A non-final Office Action was mailed January 28, 2008, an Office delay of 38 days.

A Response after non-final Office Action was subsequently filed July 24, 2008. Thus, an Office Action under 35 U.S.C. § 132, or a Notice of Allowance under 35 U.S.C. § 151, was due November 25, 2008. *See* 37 C.F.R. § 1.703(a)(2). A non-final Office Action was mailed November 26, 2008, an Office delay of 1 day.

Thus, Applicants submit that the total PTO delay under 35 U.S.C. § 154(b)(1)(A) is 502 + 38 + 1 days = 541 days.

### 2. Patent Office Delays Under 35 U.S.C. §154(b)(1)(B)

"[I]f the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application...not including (i) any time consumed by continued examination of the application requested by the application under section 132(b)...the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued." 35 U.S.C. §154(b)(1)(B). The instant application was filed on June 27, 2003. Thus, the three-year anniversary of the filing date is June 27, 2006. The above-captioned patent issued on

October 27, 2009. Thus, Applicants submit that the period of Office delay pursuant to 35 U.S.C. §154(b)(1)(B), calculated from June 28, 2006 to October 27, 2009, is 1,218 days.

### 3. Total Patent Office Delays

The patent term adjustment due to PTO delays is the sum of Office delays under 35 U.S.C. § 154(b)(1)(A) and 35 U.S.C. §154(b)(1)(B). To the extent that the period of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed. *See Wyeth v. Kappos*, 93 USPQ2d 1257, 1260 (Fed. Cir. 2010) ("If an A delay occurs on one day and a B delay occurs on a different day, those two days do not "overlap" under section 154(b)(2)").

As discussed above, the PTO delay under 35 U.S.C. § 154(b)(1)(A) occurred from August 28, 2004 to January 11, 2006, from December 21, 2007 to January 28, 2008, and from November 25, 2008 to November 26, 2008. The period of Office delay under 35 U.S.C. § 154(b)(1)(B) was between June 28, 2006 and October 27, 2009. In these periods, a total of 39 calendar days overlap: 38 days between December 21, 2007 and January 28, 2008, and 1 day between November 25, 2008 and November 26, 2008. Accordingly, Applicants submit that the total patent term adjustment due to PTO delay is 541 + 1,218 - 39 = 1,720 days.

# 4. Applicants' Delay under 37 C.F.R. §1.704

Applicants submit that the number of days of Applicants' delay is 364 days. A response to Office Action was filed on May 31, 2006 in reply to a Restriction Requirement mailed January 11, 2006. Thus, Applicants submit that a delay of 50 days was assessed by the Office in the Determination for the filing of a reply after three months from the mailing date of an Office Action. *See* 37 C.F.R. § 1.704(b).

A response to Office Action was filed on February 15, 2007 in reply to a non-final Office Action mailed August 15, 2006, a delay of 92 days. *Id*.

A supplemental response to Office Action was filed on October 30, 2007, 71 days after the August 20, 2007 filing of a response to Office Action. Thus, Applicants submit that a delay of 71 days was assessed by the Office for the filing of a supplemental reply. See 37 C.F.R. § 1.704(c)(8).

A response to Office Action was filed on July 24, 2008 in reply to a non-final Office Action mailed January 28, 2008, a delay of 87 days. See 37 C.F.R. § 1.704(b).

Finally, a Petition under 37 C.F.R. § 1.182 was filed on July 2, 2009, after the mailing of a Notice of Allowance on April 7, 2009. The Office mailed a Decision on Petition Pursuant to 37 C.F.R. § 1.182 on September 4, 2009, resulting in a delay of 64 days. See 37 C.F.R. § 1.704(c)(10) (submission of a paper after the mailing of a Notice of Allowance results in an Applicant delay starting on the date the paper was filed and ending on the mailing date of an Office action or response).

Accordingly, Applicants submit that the total of Applicants' delay is 50 + 92 + 71 + 87 +64 = 364 days.

#### Total Patent Term Adjustment 5.

In view of the above, the total patent term adjustment is the difference between total Office delays under 35 U.S.C. §154(b)(1)(A) and (B), and total Applicant delays, i.e. 1,720 -364 = 1,356 days.

#### Statement of Terminal Disclaimers Under 37 C.F.R. § 1.705(b)(2)(iii) В.

The Terminal Disclaimer filed July 24, 2008 in the above-captioned application has been withdrawn. No other Terminal Disclaimer has been filed in the above-captioned application. Therefore, as no Terminal Disclaimer exists in connection with the abovecaptioned application, Applicants submit that the correct patent term adjustment is 1,356 days.

#### C. Conclusion

The fee of \$200.00, which is due for the submission of this paper under 37 C.F.R. §1.18(e), will be paid via EFS Web. If any additional fees are due, the Commissioner is authorized to charge them to Deposit Account No. 50-3013 (referencing 417451-999055).

Respectfully submitted,

Date: May 13, 2010

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